

**Introduced by Senator Correa**

February 23, 2007

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An act to add and repeal Section 1256.01 of the Health and Safety Code, relating to public health.

**LEGISLATIVE COUNSEL'S DIGEST**

SB 891, as introduced, Correa. Health facilities: Elective Percutaneous Coronary Intervention (PCI) Pilot Program.

Existing law provides for the licensure and regulation of health facilities by the State Department of Public Health. Existing law authorizes health facilities to engage in various types of cardiac surgery.

This bill, until January 1, 2011, would establish the Elective Percutaneous Coronary Intervention Pilot Program in the department, which would authorize certain eligible acute care hospitals licensed to provide cardiac catheterization laboratory service in California that meet prescribed criteria to perform elective and scheduled primary percutaneous coronary intervention (PCI), as defined, for patients at low to medium risk at offsite surgical clinics that meet specified requirements.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Hospitals in California with cardiac catheterization laboratory
- 4 service and without cardiac surgery facilities are currently limited
- 5 to performing certain diagnostic and unscheduled interventional

1 procedures. These parameters were established by the Legislature  
2 over 20 years ago, when interventional cardiology was in its  
3 infancy, as a precautionary measure against complications.

4 (b) Technological and methodological advances in interventional  
5 cardiology have greatly improved patient outcomes, and have  
6 greatly reduced the incidences of emergency cardiac surgery.

7 (c) Multiple studies have demonstrated that removing the link  
8 between certain interventional cardiology procedures and cardiac  
9 surgery to allow therapeutic procedures to be performed for patients  
10 at low and medium risk in hospital-based cardiac catheterization  
11 laboratories, with offsite cardiac surgery facilities, results in  
12 numerous benefits to patients, including all of the following:

13 (1) Provision of diagnosis and therapeutic treatment in one  
14 procedure at one hospital, instead of two procedures at two different  
15 hospitals.

16 (2) Improved access to care and continuity of care since patients  
17 may undergo interventional cardiology procedures closer to home.

18 (3) Improved patient outcomes due to the correlation between  
19 the volume of procedures performed and the outcome (i.e., as  
20 volume increases patient outcomes improve).

21 (4) Reduction of pressure to create low-volume cardiac surgery  
22 centers primarily to support interventional cardiology, thus  
23 allowing for a better allocation of resources.

24 (d) Economic benefits associated with shorter hospital stay and  
25 reduced numbers of discharges and transfers indicates that elective  
26 percutaneous coronary intervention (PCI) at hospitals with offsite  
27 cardiac surgery is a cost effective alternative to limiting elective  
28 PCI to hospitals with onsite cardiac surgery.

29 (e) The American College of Cardiology and American Heart  
30 Association acknowledged in its report entitled “2005 Guidelines  
31 Update for Percutaneous Coronary Intervention,” that several  
32 studies of elective PCI with offsite cardiac surgery have reported  
33 satisfactory results based on careful case selection and well-defined  
34 arrangements for immediate transfer to a surgical program if  
35 needed.

36 (f) The Legislature finds that clinical data and experience  
37 relating to elective PCI at hospitals with offsite cardiac surgery  
38 need to be gathered in order to ensure that California licensed  
39 health care facilities and physicians will achieve satisfactory results  
40 and maintain a high standard of care for patients. For the foregoing

1 reasons, it is the intent of the Legislature to establish the elective  
2 Percutaneous Coronary Intervention (elective PCI) Pilot Program  
3 to allow certain general acute care hospitals that are licensed to  
4 perform cardiac catheterization laboratory service in California to  
5 also perform scheduled elective percutaneous transluminal coronary  
6 angioplasty (PTCA) and stent placement for patients at low and  
7 medium risk at offsite cardiac clinics if those clinics have adequate  
8 surgical backup.

9 SEC. 2. Section 1256.01 is added to the Health and Safety  
10 Code, to read:

11 1256.01. (a) The Elective Percutaneous Coronary Intervention  
12 (PCI) Pilot Program is hereby established in the department. The  
13 purpose of the pilot program is to allow the department to authorize  
14 six general acute care hospitals licensed to provide cardiac  
15 catheterization laboratory service in California to perform elective  
16 and scheduled percutaneous coronary intervention and stent  
17 placement for low- to medium-risk patients at offsite cardiac clinics  
18 that meet the requirements of this section.

19 (b) For purposes of this section, the following terms have the  
20 following meanings:

21 (1) "Elective Percutaneous Coronary Intervention (elective  
22 PCI)" means scheduled percutaneous transluminal coronary  
23 angioplasty (PTCA) and stent placement.

24 (2) "Eligible hospital" means a general acute care hospital  
25 without cardiac surgery services that has a licensed cardiac  
26 catheterization laboratory and is in compliance with all applicable  
27 state and federal licensing laws and regulations.

28 (3) "Interventionalist" means a licensed cardiologist who meets  
29 the requirements for performing elective PCI at a pilot hospital.

30 (4) "Pilot hospital" means a hospital participating in the Elective  
31 PCI Pilot Program established by this section.

32 (5) "Primary Percutaneous Coronary Intervention (primary  
33 PCI)" means percutaneous transluminal coronary angioplasty  
34 (PTCA) and stent placement that is emergent in nature.

35 (6) "Receiving hospital" means a licensed general acute care  
36 hospital with cardiac surgery services that has entered into a  
37 transfer agreement with a pilot hospital.

38 (7) "Transfer agreement" means an agreement between the  
39 eligible hospital and the receiving hospital that meets all of the  
40 requirements of this section.

1 (c) (1) To participate in the pilot program, an eligible hospital  
2 shall meet all of the following criteria:

3 (A) The eligible hospital has an interventionalist and cardiac  
4 catheterization laboratory staff on-call and available 24 hours a  
5 day, seven days a week.

6 (B) The eligible hospital performs at least 36 primary PCI  
7 procedures and 800 diagnostic cardiac catheterizations annually.

8 (C) The eligible hospital includes in its application evidence of  
9 having primary PCI available 24 hours a day, seven days a week,  
10 including, but not limited to, the following:

11 (i) Cardiac catheterization laboratory policies and procedures.

12 (ii) Emergency room policies and procedures applicable to  
13 transfers to the cardiac catheterization laboratory.

14 (iii) Volume and relevant patient outcome, including, but not  
15 limited to, complication rates of primary PCI procedures performed  
16 annually for the past three years.

17 (iv) Volume and relevant patient outcome, including, but not  
18 limited to, complication rates of diagnostic cardiac catheterizations  
19 performed annually for the past three years.

20 (D) The eligible hospital providing elective PCI, has an  
21 interventionalist on staff who meets both of the following  
22 requirements:

23 (i) Holds board certification by the American Board of Internal  
24 Medicine in Interventional Cardiology and Cardiovascular  
25 Diseases.

26 (ii) Performs a minimum of 125 primary or elective PCI  
27 procedures per year.

28 (E) The eligible hospital includes in its application evidence of  
29 the qualifications of each interventionalist at the hospital who may  
30 perform elective PCI, including, but not limited to, the following:

31 (i) Proof of a valid, unrestricted California license from a  
32 medical board.

33 (ii) The interventionalist's curricula vitae.

34 (iii) The interventionalist maintains valid privileges at the  
35 eligible hospital.

36 (iv) The interventionalist's total volume of PCI procedures, the  
37 annual volume of those procedures for the past three years, and  
38 information regarding any formal investigation or disciplinary  
39 action regarding PCI procedures taken at any hospital where the  
40 interventionalist has been on staff.

1 (F) The eligible hospital designates a program director who is  
2 an interventionalist with career experience of more than 1,000  
3 elective and primary PCI procedures who meets all other  
4 requirements for an interventionalist described in this section.

5 (G) The eligible hospital employs cardiac catheterization  
6 laboratory staff who are experienced and trained in interventional  
7 procedures and equipment, including, but not limited to,  
8 hemodynamic monitoring and intra-aortic balloon pump  
9 management.

10 (H) The cardiac catheterization laboratory staff at an eligible  
11 hospital complies with all of the following:

12 (i) The eligible hospital has policies and procedures in place for  
13 providing quality cardiac care, including, but not limited to,  
14 continuing education requirements and required competencies.

15 (ii) The eligible hospital complies with all existing laws and  
16 regulations pertaining to catheterization laboratory staff, including  
17 applicable licensure and certification.

18 (iii) The eligible hospital demonstrates competency in caring  
19 for and managing arterial sheaths, including, but not limited to,  
20 removal of those sheaths.

21 (I) An eligible hospital shall also provide in its application  
22 evidence of the cardiac catheterization laboratory staff's  
23 competency to assist in performing elective PCI procedures and  
24 care for elective PCI patients, including, but not limited to, the  
25 following:

26 (i) A description of all cardiac catheterization laboratory policies  
27 and procedures, including those addressing the addition of elective  
28 PCI procedures.

29 (ii) A description of all staff positions and principal  
30 accountabilities of all cardiac catheterization staff and the role of  
31 each position in the proposed elective PCI procedures.

32 (iii) Evidence of demonstrated competencies for all cardiac  
33 catheterization staff.

34 (iv) A description of continuing education requirements and  
35 evidence of completion for required education for all cardiac  
36 catheterization staff.

37 (J) An eligible hospital shall ensure that posttreatment nursing  
38 care for patients undergoing elective PCI shall be provided in an  
39 intensive care unit by appropriately trained and experienced nurses.  
40 The eligible hospital shall also demonstrate sufficient capacity in

1 the intensive care unit to provide posttreatment care for patients  
2 undergoing elective PCI.

3 (K) An eligible hospital shall ensure that posttreatment care in  
4 the intensive care unit by nurses competent in the care and recovery  
5 of patients who have undergone elective PCI, as demonstrated by  
6 factors, including, but not limited to, the following:

7 (i) Compliance with all existing state laws and regulations,  
8 including, but not limited to, registered nurse licensure and Basic  
9 Life Support and Advanced Cardiac Life Support certification.

10 (ii) Experience in hemodynamic monitoring and intra-aortic  
11 balloon pump management.

12 (iii) Compliance with an eligible hospital's policies and  
13 procedures for providing critical care.

14 (iv) All required competencies (eligible hospital, nursing, and  
15 unit specific) and continuing education requirements.

16 (v) Demonstrated competency in caring for and managing  
17 arterial sheaths, including, but not limited to, removal of the sheath.

18 (L) An eligible hospital shall provide in its application evidence  
19 of its proposed posttreatment care, including, but not limited to,  
20 the following:

21 (i) The intensive care unit's policies and procedures applicable  
22 to the care of patients recovering from elective PCI procedures,  
23 including, but not limited to, how the eligible hospital will ensure  
24 sufficient space in the intensive care unit for patients who have  
25 undergone those procedures.

26 (ii) Position descriptions and principal accountabilities of all  
27 intensive care unit staff that will provide posttreatment care to  
28 patients recovering from elective PCI procedures.

29 (iii) Required competencies and continuing education  
30 requirements, as well as proof of completion of these requirements,  
31 for nurses providing posttreatment care to patients recovering from  
32 elective PCI procedures.

33 (M) The eligible hospital shall provide elective PCI in a cardiac  
34 catheterization laboratory using appropriate equipment, including,  
35 but not limited to, imaging systems capable of transferring cardiac  
36 catheterization images to the receiving hospital, resuscitative  
37 equipment, intra-aortic balloon pump support, and the full range  
38 of interventional equipment necessary for performing elective PCI.  
39 An eligible hospital shall further provide in its application evidence  
40 demonstrating that its cardiac catheterization laboratory is

1 sufficiently equipped to perform elective PCI, including, but not  
2 limited to, the following:

3 (i) Cardiac catheterization laboratory policies and procedures  
4 relating to the performance of elective PCI.

5 (ii) List of equipment available in an eligible hospital's cardiac  
6 catheterization laboratory.

7 (iii) Description and proof that cardiac catheterization laboratory  
8 equipment is appropriately serviced and maintained.

9 (N) The eligible hospital shall provide letters, board resolutions,  
10 or comparable evidence of approval of, and support for,  
11 participation in the elective PCI Pilot Program by the administrative  
12 staff and governing body of both the eligible hospital and the  
13 receiving hospital.

14 (O) The eligible hospital shall have a transfer agreement that  
15 ensures the immediate and efficient transfer of patients, within 60  
16 minutes, 24 hours a day, seven days a week, from the eligible  
17 hospital to the receiving hospital. The time for transfer of patients  
18 shall be calculated from the time it is determined that transfer of  
19 a patient for emergent cardiac surgery is necessary at the eligible  
20 hospital, to the time that the patient arrives at the receiving hospital.

21 (P) The transfer agreement and the transfer policies and  
22 procedures shall include, at a minimum, all of the following:

23 (i) An arrangement with an ambulance company for transport  
24 by ambulance, or other appropriate means, to be onsite at the  
25 eligible hospital during each elective PCI procedure during the  
26 first six months the eligible hospital is enrolled in the pilot program  
27 or during the first 20 elective PCI procedures performed at eligible  
28 hospital, whichever is longer. After the first six months or the first  
29 20 elective PCI procedures, whichever time period is longer, the  
30 eligible hospital may remove the requirement that an ambulance,  
31 or other form of transportation, be available onsite so long as the  
32 eligible hospital is still able to ensure that the 60-minute maximum  
33 patient transfer time is achieved 24 hours a day, seven days a week.

34 (ii) A description of how the eligible hospital's cardiac  
35 catheterization laboratory staff are to communicate and coordinate  
36 with the receiving hospital regarding the transfer of a patient.

37 (iii) A requirement that an interventionalist and a qualified  
38 cardiac catheterization laboratory nurse, trained in hemodynamic  
39 monitoring and intra-aortic balloon pump management, accompany  
40 the patient during transportation to the receiving hospital.

1 (iv) A description of how the receiving hospital will  
2 communicate and coordinate with the eligible hospital regarding  
3 the transfer of a patient.

4 (v) A description of how the patient will be cared for at the  
5 receiving hospital if an operating room has not been prepared by  
6 the time the patient arrives at the receiving hospital.

7 (vi) A description of how the receiving hospital will ensure  
8 appropriate postsurgical care for patients who are transferred,  
9 including admission to receiving hospital's intensive care unit.

10 (2) The application shall also include copies of the transfer  
11 agreement and the transfer policies and procedures from both the  
12 eligible hospital and the receiving hospital.

13 (Q) The eligible hospital shall develop and complete a  
14 performance improvement plan dedicated to monitoring and  
15 evaluating the elective PCI program to ensure patient safety and  
16 efficacy, which shall also include all of the following:

17 (i) Enrollment in the American College of Cardiology National  
18 Cardiovascular Data Registry, or a comparable national  
19 cardiovascular data registry.

20 (ii) A performance improvement plan that includes, but is not  
21 limited to, the following:

22 (I) A system for regularly reviewing and assessing the results  
23 from the eligible hospital's chosen national cardiovascular data  
24 registry.

25 (II) A system for monitoring Interventionalist privileges  
26 including reviewing continuation of interventionalist privileges in  
27 elective PCI, based on outcome rates, at least every two years.

28 (III) A system for performing ongoing quality assessment  
29 comparing results with current benchmarks, and performing risk  
30 stratification of complication rates.

31 (IV) A plan for conducting performance reviews on every  
32 elective PCI procedure, assessing patient complication rates and  
33 root cause analysis of problems associated with complications,  
34 and taking action as necessary in accordance with the eligible  
35 hospital's performance improvement plan.

36 (iii) The receiving hospital shall develop a performance review  
37 plan that addresses how it will monitor the transfer of each patient  
38 to its facility from the eligible hospital.

39 (iv) The eligible hospital and the receiving hospital shall develop  
40 a system that allows each facility to share with the other relevant



1 performance improvement information regarding the elective PCI  
2 Pilot Program and related peer review information.

3 (v) The application shall include evidence of both the eligible  
4 hospital and the receiving hospital's performance improvement  
5 plans, including, but not limited to, the following:

6 (I) The eligible hospital's performance improvement policies  
7 and procedures.

8 (II) The receiving hospital's performance review policies and  
9 procedures.

10 (R) The eligible hospital shall provide evidence in its application  
11 that demonstrates the use of rigorous case selection for patients  
12 undergoing elective PCI that meets all of the following  
13 requirements:

14 (I) Only patients at low to medium risk may undergo elective  
15 PCI at an eligible hospital. Patient selection shall be based on the  
16 interventionalist's professional medical judgment which may  
17 include, but is not limited to, consideration of the patient's clinical  
18 risk, the patient's lesion risk, and the patient's overall health status.

19 (II) For purposes of this clause, "clinical risk" means the  
20 patient's clinical capacity to compensate in the event of unexpected  
21 arterial blockage. "High clinical risk" may include, but is not  
22 limited to, the following features: severe left ventricular heart  
23 function with ejection fraction of 25 percent or less; severe left  
24 main or 3-vessel disease unprotected by prior bypass surgery; or  
25 the target lesion jeopardizes over 50 percent of the remaining viable  
26 heart muscle.

27 (III) For purposes of this clause, "lesion risk" means the  
28 likelihood that elective PCI will cause arterial blockage based on  
29 characteristics, including, but not limited to, length, tortuosity,  
30 location, or other anatomical features. "Increased lesion risk" may  
31 include, but is not limited to: long blockages (> 4 cm length) in  
32 small vessels; excessive tortuosity of calcified arteries; location  
33 in an extremely angulated calcified arteries; inability to protect  
34 major side branch arteries; or degeneration of older vein grafts  
35 with a severe amount of blood clots.

36 (ii) Patients at high clinical and increased lesion risk shall not  
37 be eligible for inclusion in the elective PCI Pilot Program.

38 (iii) The receiving hospital shall review and approve the eligible  
39 hospital's patient selection criteria.

1 (S) The eligible hospital shall demonstrate evidence of the  
2 process for obtaining written informed consent from patients prior  
3 to undergoing elective PCI. The application shall include a copy  
4 of the eligible hospital's informed consent form applicable to  
5 elective PCI.

6 (T) The eligible hospital shall include with its application an  
7 implementation plan describing how the eligible hospital will  
8 implement the pilot program following selection and approval by  
9 the department.

10 (U) Consistent with this section, the department shall invite  
11 eligible hospitals to submit an application to participate in the  
12 elective PCI Pilot Program. The applications shall include sufficient  
13 information to demonstrate compliance with the standards set forth  
14 in this section, and additionally include the effective date for  
15 initiating elective PCI service, the general service area, a  
16 description of the population to be served, a description of the  
17 services to be provided, a description of backup emergency  
18 services, the availability of comprehensive care, and the  
19 qualifications of the general acute care hospital providing the  
20 emergency treatment. The department may require that additional  
21 information be submitted with the application. Failure to include  
22 any required criteria or additional information shall disqualify the  
23 applicant from the application process and from consideration for  
24 participation in the pilot program. The department may select up  
25 to six general acute care hospitals for participation in the elective  
26 PCI Pilot Program based on their ability to meet or exceed the  
27 criteria described in this section.

28 (V) (i) An advisory oversight committee comprised of one  
29 interventionalist from each eligible hospital and a representative  
30 of the department shall be created to oversee, monitor, and make  
31 recommendations to the department concerning the pilot program.  
32 The advisory oversight committee shall submit at least two reports  
33 to the department during the pilot period. The oversight committee  
34 shall conduct a final report at the conclusion of the pilot program,  
35 including recommendations for the continuation or termination of  
36 the pilot program.

37 (ii) If at any time an eligible hospital that participates in the  
38 pilot program fails to meet the criteria for being a pilot hospital or  
39 fails to safeguard patient safety, as determined by the department,

1 that pilot hospital shall be removed from participation in the pilot  
2 program by the department.

3 (W) An eligible hospital that participates in the pilot program  
4 shall provide annual reports to the department and the oversight  
5 committee that include statistical data and patient information  
6 relating to the number of elective PCI procedures performed, the  
7 interventionalists performing elective PCI procedures, and the  
8 outcomes of those procedures. In addition, eligible hospitals shall  
9 include in the report recommendations, if any, for modifications  
10 to the pilot program and any other information the eligible hospitals  
11 deem relevant for evaluating the success of the pilot program in  
12 delivering improved patient care.

13 (d) This section shall remain in effect only until January 1, 2011,  
14 and as of that date is repealed, unless a later enacted statute, that  
15 is enacted before January 1, 2011, deletes or extends that date.